Phantom Update

- The Evelhoch /QIBA phantom prototype is being fabricated in the MD Anderson machine shop and should be available within the month
  - High purity NiCl2 and NaCl, polypropylene centrifuge tubes have been received.
  - RSNA will reimburse costs up to $500
  - Dr Jackson will create the mixtures based on the deltaR1 values discussed on the last tcon, taking into account Dr Rosen’s suggestions of February 11th.
- Second phantom and protocols (Drs Jackson/Karczmar) received at Duke; ready to begin image acquisition on Philips platform
  - Phantom to be shipped back to MDACC, then to UC Davis upon completion of scanning
- Dr Ashton has agreed to process the VB17 data from UPenn, as time allows.
  - Dr Rosen to send data to Dr Ashton.
- Dr Rosen to confirm with Dr Jackson that phantom is to be sent to Dr Karczmar at UChicago (address needed)
  - Use same parameters as Duke

Roadmap

- $K_{trans}$ as a validated biomarker is the ultimate goal
- DCE as a pharmacodynamic biomarker is evident, but not clear how to establish that impact on vasculature is related to outcome
  - Antiangiogenic approach has not been proven to affect outcome
  - Outcomes are needed to engage regulators
- Need technical assessment to ensure $K_{trans}$ is a viable biomarker before measuring treatment response or prognostic value
- Consider whether it is necessary to be able to answer the following questions
  - Does a drop in $K_{trans}$ indicate improved outcome?
  - Is a high $K_{trans}$ prognostic for angiogenic treatment?
- Comparability of $K_{trans}$ between centers not yet achievable
Establishing a standard and methodology will permit comparison of data from individual studies to answer the above questions.

- Standardization needed to have confidence in results
- Need to decide whether DCE-MRI is at a stage to prepare briefing document to position a pre-agreement with the FDA on work that needs to be done
- Agreement that an endpoint and roadmap need to be established
- Results of phantom studies will help identify problems
- Test-retest stage can then follow
- Dr Zahlmann to draft basic outline for review before next call
- Qualification activities not the purview of this Committee

Next Steps:
- Dr Rosen to send UPenn data to Dr Ashton for Siemens VB17 analysis
- Dr Karczmar to supply shipping address to Dr Rosen
- Dr Zahlmann to summarize next steps to be taken for group review
- Next call scheduled for Wednesday, March 31, 2010 at 11 AM CST